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Hepatitis C Review

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Liver Biopsy

Douglas T. Dieterich, MD

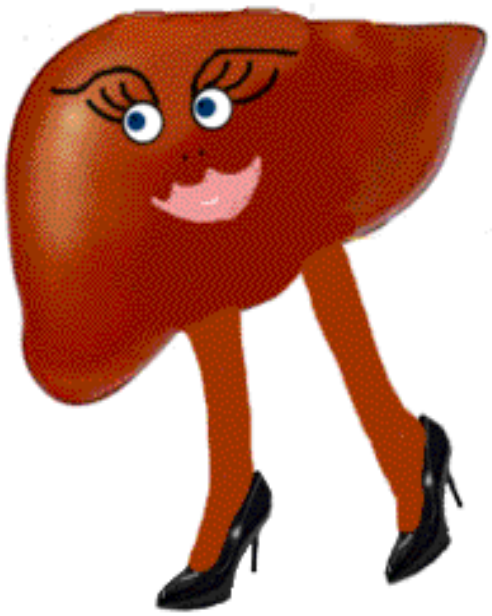
The mere mention of the two words "Liver Biopsy" strikes fear into people's hearts. They have heard all sorts of horrific things about the procedure: it's more painful than childbirth, the needle is the size of a harpoon, there are large incisions and scars. Nothing could be further from the truth. It is a very benign procedure that is vital to diagnose liver disease.

Why do a liver biopsy in the first place? In people with viral hepatitis B and C it really determines the stage of damage done by the viruses. The pathologist usually grades the fibrosis or scarring of the liver on a 0-4 scale. Four is cirrhosis and is often considered irreversible (although recent data seems to contradict that). We try to avoid that outcome whenever possible. Zero is no fibrosis, which means there has been no damage to the liver yet. The NIH guidelines for treating hepatitis C recommend treatment for any fibrosis of grade 1 or more. We also know the time it usually takes for a biopsy to progress from one grade to another. The median time (the time for half the people) to progress to cirrhosis from a grade 3 biopsy is about 18 months. While the time to cirrhosis from a grade 1 biopsy is about 12 years, the liver biopsy can be very helpful information in determining when to treat someone's hepatitis. If they want to wait 6 or 12 months, that is fine with a grade 1 biopsy, but quite scary with a grade 3! It is also very important to know if someone has cirrhosis. If they do we need to look inside their esophagus for varicose veins called varices that can bleed catastrophically. When we look we can also treat them with rubber banding or injection and prevent them from bleeding. Progression of hepatitis is, in general, accelerated in HCV/HIV co-infected individuals. Studies so far find HCV progression in co-infected patients may progress 1.5 to 4 times more quickly than in patients with HCV infection alone. I always add one stage to my mental calculations when I have an HIV+ patients' liver biopsy.

There are other reasons to do a biopsy. The biopsy can help us diagnose other liver diseases that we might have missed. For example, a patient of mine with hepatitis C had a biopsy a few years ago to stage his disease. The results showed that he suffered from vitamin A overdose and that was damaging his liver more than the hepatitis. He was unaware he was taking too much of the potentially liver toxic vitamin A. He stopped it. Then we repeated the biopsy a year later, and the

Do you Love your Liver?

Olivia, our spokes-liver wants to know.



IN THIS ISSUE:

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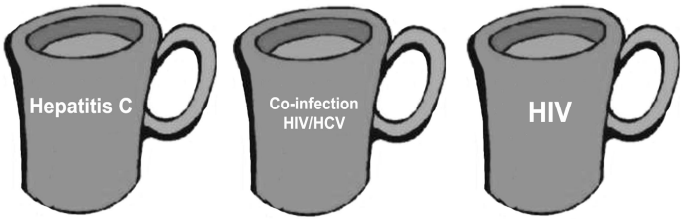
NATAP NATIONAL AIDS TREATMENT ADVOCACY PROJECT
EDUCATING COMMUNITIES ABOUT HIV AND HEPATITIS

hepatitis C damage was now visible. He is now getting treatment for his hepatitis C.

In patients with HIV of course everything is more complicated, and the liver biopsy may be even more important. One patient with both HIV and HCV on his biopsy demonstrated that he also had hemochromatosis, a disorder of iron metabolism that can be treated by donating blood. Another woman whose biopsy I just did recently had a large amount of fat on the biopsy as well as cirrhosis. This kind of fat was characteristic of the toxicity of the D4T that she was taking. We substituted another drug for her D4T and will treat her HCV in a few months after the toxicity subsides. Finally, in HIV patients the AST and ALT blood tests which everyone calls liver "function" tests but are not really function tests at all, may not be elevated but the biopsies can still reveal cirrhosis or severe liver damage. This is more common in HIV+ patients, but can still happen in the HIV negative patient as well.

So now you know why we do a biopsy. Let's talk about how we do it. First we make an appointment for a blood test within a week of the biopsy to make sure that your blood will clot well. That usually consists of a platelet count and a Prothrombin Time Ratio test. Some hospitals (and the test is done in the hospital) also get a blood type test at the same time. It is about a 4-5 hour stay in the hospital. I like to sedate a patient before the biopsy, although many doctors do not routinely do this. I use Demerol and Versed, which is like Valium to relax people. It is not anesthesia, but like a cocktail or two to help you relax (obviously alcohol is not encouraged in people with liver disease). After the nurse gives you the injection, we wait a few minutes for the drugs to take effect. Then we outline the spot on your right side where we will insert the needle. We clean it thoroughly with iodine and let it dry. Next comes the lidocaine, which is the local anesthesia. It first burns for a few seconds as it goes in and then the area becomes numb. We take that needle out and put in a slightly longer one to numb the deeper area. Finally we use the biopsy needle. We usually ask you to take a breath in, blow it all the way out and then hold it for a second or two. After we do the biopsy most patients say "Is that it?" Some people feel a little pressure or punch some do not. Afterwards we ask you to lie on your right side for a few hours to prevent bleeding and stay in bed for a few more hours. Some people feel a little right shoulder pain for an hour or so after the biopsy. The most common risk associated with liver biopsy is bleeding. Less than one in a thousand people will have significant bleeding, and less than one in ten thousand may have a fatal outcome. When you are ready to go home, you will be instructed not to take aspirin or ibuprofen for a week or so. Tylenol is fine for pain, but it is rare that there is any pain from the liver biopsy site. Also we would recommend no strenuous exercise that might trigger bleeding.

It generally takes several days to a week for the pathologists to complete their evaluation of a biopsy. I usually suggest an appointment to discuss the results so we can put the whole thing in context. However many patients are anxious and want the results over the phone as soon as possible, which is understandable. An appointment should still follow that conversation so that there are no misunderstandings and a treatment or no treatment decision is a well-informed one. If you need a liver biopsy then you should certainly not let irrational fears or bad information prevent you from having one. The information obtained is very valuable and can only assist you and your doctor in making the best possible decisions concerning your health.



Circle of Support in SoHo

Dawn Schuk, MHA

There is great news for individuals co-infected with Hepatitis C (HCV) and HIV. NATAP has started a group for co-infection. We realize these individuals are dealing with different issues from those who are infected with only one of the viruses. We will be holding our next meeting on May 13th from 5-7pm at our office. This support group will meet the second Tuesday of every month.

The response has been overwhelming; we have had calls from all of the boroughs. Reinforcing the need to address the issue of co-infection. Our hope is for the support group to be a foundation for those who truly need it. We will also serve as a resource to the group in providing guests to speak on a variety of issues that may affect the co-infected individual.

If you have any questions please feel free to call Dawn at 212-219-0106 or 1-888-26-NATAP.

Dawn Schuk, MHA
Hepatitis C Outreach and Community Development Coordinator

HCV/HIV Co-infection: The Menacing Challenge of the Third Decade of HIV

About 5 years ago I took the antibody test for the hepatitis C virus (HCV) and discovered I was positive for the virus. Back then HIV doctors were not routinely testing their patients for hepatitis C, but I had heard that I might have this virus considering my background. About 20 years ago, I used intravenous drugs for a number of years and unfortunately shared used needles and drug paraphernalia (cooker, water, cotton). After testing HCV+ I had the standard diagnostic tests performed: HCV viral genotype, HCV viral load, and a biopsy, in addition to routine liver-related bloodwork including LFTs (liver enzyme function tests: ALT, AST etc). Unfortunately, my biopsy showed I had compensated cirrhosis.

I have had two courses of HCV therapy. About 4 years ago I was treated with standard interferon plus ribavirin, but had no reduction in my HCV viral load. About 2 years ago I started a course of treatment with pegylated interferon plus ribavirin, and had a very swift positive result. My HCV viral load became undetectable within several weeks and my high ALT was normalized. I continued therapy for 18 months until August 2002. Five months after stopping therapy my viral load remained undetectable and my ALT was normal. I continue to monitor my situation and remain hopeful. The current standard of care for treating the hepatitis C virus is pegylated interferon in combination with ribavirin. Pegylated interferon is a subcutaneous injection taken once per week in the belly. Ribavirin is taken in the form of pills twice daily.

Why has NATAP taken on HCV and HCV/HIV co-infection in a big way?

The treatment for HIV, HAART therapy (3 or 4 HIV drugs), can be very effective in sustaining an individual's health and longevity. Many HIV-infected individuals are doing well, working, and will live productive and relatively healthy lives for what may approach a normal life-span. However, in this third decade of HIV we find that 20% to 30% of HIV-infected individuals have HCV, that is 200,000 to 300,000 individuals; and 60-90% of individuals infected with HIV by injection drug use (IDUs) have HCV. Findings from studies suggest HCV and liver related complications are now the leading cause of death in HIV. In addition, study results show that HIV accelerates the progression of hepatitis C disease by 2 times or more. Yet, very little attention is paid to what has become an epidemic—co-infection with HIV and the hepatitis C virus.

We know that HCV is the leading blood-born disease in the US. Regarding how many people overall in the US have the hepatitis C virus, the NHANES study found about 1.8% of the entire US population has HCV, that is about 4 million people; and about 2.7 million people have chronic HCV. However, everyone agrees these figures are underestimates and this study was not well performed. The study did not count incarcerated and homeless individuals. We have not had studies counting how many people have HCV in any specific state or city in the US. Some states and cities are trying to conduct these studies now but there is little financial support for this.

We need funding from the Federal government to support programs addressing certain needs related to co-infection and for individuals who have hepatitis C but do not have HIV along with it. We do not have funding so that community-based organizations can perform street outreach for testing and prevention for hepatitis C. All community-based AIDS service organizations that do HIV testing and counseling could easily and inexpensively incorporate HCV testing and counseling. We need public awareness programs to promote prevention and medical care. We need treatment and prevention education programs for patients and community workers, and treatment education programs for medical professionals including HIV doctors. We need well designed natural history studies that can better characterize our understanding of the progression of HCV in co-infected individuals and provide answers to additional unanswered but important questions. We need to have a better understanding of how many individuals are co-infected in your city and state. A few studies have been conducted and that's how we estimate there are 200,000 to 300,000 individuals with co-infection, but we do not know much more than that. For example, we do not know how many individuals in Florida, Texas, California or New York City have HCV/HIV co-infection.

If we were able to test all persons at-risk for HCV we would probably not be able to provide care to all of them. The HIV medical care system does not have the capacity to absorb and treat all co-infected individuals. As well, the care system in the US probably does not have the capacity to absorb and treat all HCV mono-infected individuals.

IV drug use and sharing drug using paraphernalia has become the leading cause of transmission for HCV, but ironically IDUs often have difficulty in accessing HCV treatment and care services. However, pilot studies have demonstrated that IDUs can respond well to HCV therapy if they receive adequate support services. To read more about this see Dr. Diana Sylvestre's article in this issue of our newsletter.

In order to further this cause, NATAP co-sponsored a Congressional Briefing on March 25, 2003 in association with two leading members of the Congressional Black Caucus. You can read about this well received event in this issue of our newsletter. I hope this briefing will help in securing the funding for programs we need for co-infected individuals.

Jules Levin
Founder/Executive Director, NATAP

Diagnosing, caring for, and treating co-infected patients requires attending to many unique circumstances, and requires a multi-disciplenary team of medical and care providers. Studies show that patients are more successful with HCV therapy when they can access such a team of care providers. This article by Heather Timmerman, Physician's Assistant who runs the co-infection clininc at Brooklyn Hospital, is a good example of what co-infected patients need in terms of care and treatment and a multi-disciplenary approach to addressing comprehensively the needs of co-infected patients

-Jules Levin

The Path Center in Brooklyn Hospital Center

Heather Timmermans, RPA-C

The PATH Center (Program for AIDS Treatment and Health) of the Brooklyn Hospital Center, is a Ryan White Title III program and a New York State AIDS Designated Center, which provides comprehensive primary care for HIV/AIDS and Hepatitis C (HCV) infected individuals.

The PATH Center has a multidisciplinary team that consists of medical providers, case managers, social workers, a dental hygienist, a psychiatrist, nutritionist, HIV counselors, an outreach coordinator, and treatment adherence specialists. The PATH Center has English, Spanish and Creole speaking medical providers and case managers. The clinic has linkages with over 50 community-based agencies, three of which have case managers outstationed in the PATH Center. In addition, peer educators who are co-infected with HIV and HCV and being treated for both diseases work in the clinic and provide excellent support for the PATH Center clients.

The PATH Center is under the administration of Dan Sendzik and is under the medical direction of Dr. Leonard Berkowitz. Dr. Berkowitz has been named as one of New York Magazine's Best Doctors in New York City for the past five years.

Heather Timmermans, RPA-C is the Director of Clinical Services and runs a weekly HIV-HCV Co-infection clinic. Approximately 30% of the PATH Center's HIV positive clients are co-infected with HCV. Given the medical advances in the management of HIV, many HIV positive patients are living well with HIV, but are getting sick from HCV.

In the PATH Center, all HIV positive clients are screened for Hepatitis A, B and C. Patients who are not already immune are vaccinated against Hepatitis A and B. Patients who are HCV positive or have clinical suspicion of HCV undergo testing for HCV viral load by PCR to confirm chronic infection.

Each HCV client is individually evaluated for treatment with pegylated interferon and ribavirin. Patients who were nonresponders or relapsers on interferon/ribavirin therapy are reconsidered for starting pegylated interferon and ribavirin therapy. Patients who meet the guidelines for HIV therapy generally are stabilized on antiretroviral therapy prior to the initiation of HCV therapy. If antiretroviral therapy is not indicated for an HIV-HCV co-infected client, the patient is then evaluated for HCV treatment.

HIV positive patients have their CD4 cell counts and HIV viral loads monitored regularly. In addition, all chronically infected HCV patients specifically have AST, ALT, alkaline phosphatase, platelets, total and direct bilirubins, albumin, and PT/PTT ordered. Abdominal sonograms and alpha feto-protein markers are performed at least annually to screen for hepatocellular carcinoma. Pre-treatment clinical and laboratory evaluation also include HCV genotyping, TSH, RPR, CBC, lipids, ANA, pregnancy testing, alcohol and depression screening and ophthalmologic examination. HCV positive patients are seen by the psychiatrist prior to initiation of HCV therapy. A liver biopsy is strongly recommended to evaluate the severity of inflammation and fibrosis and to stage the liver disease. Liver biopsies at the PATH Center are performed either by the gastroenterologists or interventional radiologists. Clients on HCV therapy are followed closely for adverse events and side effects and are given 24-hour emergency phone numbers to access if needed.

It is critical that patients infected with HIV, HCV or both are treated by experienced medical and mental health care experts in these fields. Treating providers must be knowledgeable in the current standards of care in the rapidly changing fields of HIV and HCV. Optimal knowledge of side effect management and potential drug interactions between HIV antiretrovirals, HCV therapies and psychotropics are required.

There is a strong need for more specialized HIV-HCV Co-infection clinics to be established. It can be difficult in many HIV clinics for co-infected patients to receive the extra time needed to thoroughly address all aspects of their care in a regular visit. Clinics that provide comprehensive on-site medical, mental health, case management, social work, nutrition, treatment adherence, substance abuse treatment, support groups and peer education services are critical to the success of the HIV-HCV client. It is important to enable a patient to become a partner in his or her care. A strong relationship between the support staff and the patient will help sustain the patient's motivation and adherence and improve response to therapy.

The Path Center in Brooklyn Hospital Center has 2 locations

121 DeKalb Avenue Brooklyn , NY 11201	**100 Parkside Avenue Brooklyn, NY 11226**

(718) 940-5930

Diet and Hepatitis C

Jocelyn Rodriguez, MPH, RD, CDN

Jocelyn Rodriguez, MPH, RD, CDN is a nutritionist specializing in HIV/HCV at DAYTOP Villiage, a large drug treatment organization. She received her graduate training at University of California at Berkeley and is an alumnus of Hunter College, CUNY. Presently she works with the substance abuse population, where the rate of Hepatitis C infection is high.

The HIV epidemic redefined interdisciplinary medical care toward infectious chronic diseases. As infectious diseases became manageable via medication, education and lifestyle changes, nutritional intervention played a greater role in helping to achieve good quality of life. Hepatitis C embodies this new paradigm (approach to treatment of diseases), and nutritional advice on eating habits and supplements has proliferated since Hepatitis C was identified in the early 1990's from the former Non A, Non B Hepatitis.

Dietary interventions have been used since the first days of treating cirrhosis, but seldom have doctors and dietitians advised dietary changes as prevention of or delay to the progression of the liver toward a cirrhotic state. The Europeans are ahead of the United States in focusing on liver health, i.e. milk thistle for liver function assistance and amino acid formulas for liver regeneration, however, results remain inconclusive. Nonetheless, we may yet benefit from their treatment suggestions in the management of Hepatitis C.

Editorial Note: recently reported research data suggested that milk thistle might cause a drug interaction with HIV medications, thus affecting the blood levels of HIV medications. At the IAS Conference in Buenos Aires (July 6-11, 2001), Steve Piscitelli (Pharmacologist) reported on new recently completed research from the NIH. Preliminary results of exploring indinavir (Crixivan) and milk thistle for 3 weeks did not show clinically significant interactions. This suggests that milk thistle should not have a drug interaction with HIV antiretroviral protease inhibitors and NNRTIs. However, there is a question whether milk thistle is effective. There is a little preliminary research suggesting milk thistle may be helpful for the liver. However, the evidence is not strong. In taking herbal supplements for the liver, the question one needs to ask is –is the herb potentially harmful to me? Some herbs have been shown to be harmful to the liver. It appears as though milk thistle may not be harmful, but the data on interactions with HIV meds from Steve Piscitelli is preliminary and still being analyzed.

The question remains whether we should be proactive about early dietary changes for persons infected with Hepatitis C but who have not manifested symptoms of liver failure? While an ounce of prevention is worth a pound of cure, changing eating habits is very difficult to make and harder to adhere to. Recommending vitamin and herbal supplements can get expensive and may not significantly increase quality of life. This by no means implies that persons with Hepatitis C should not pay attention to their dietary habits and nutritional requirements. Each individual will need to be evaluated by a dietitian with experience in liver disease to determine his or her own requirements. The reason for this is because people do not select their diets based on physical and/or medical requirements alone, but also from their cultural upbringing, access to food/meals, and certain habits set by choice and convenience.

A nutritional foundation of dietary practices should be the guide for persons with Hepatitis C, especially at times when there are no gastrointestinal symptoms and liver function tests are normal or mildly elevated with no other clinical abnormalities:

1. Get half of your daily calories in carbohydrates. Whole grain starches, vegetables and fruits should be the mainstay of carbohydrates.

Sugar and sugary foods, like donuts and candy bars, should be minimized.

2. Keep protein intake up. Have some protein at every meal. Portion matters more than kind of protein. Make sure to include beans and tofu products, nuts, and dairy products.

3. Moderate fat consumption. Cutting back sugary foods tend to reduce fat intake. Nuts and tofu, which are protein sources, have a healthy amount of unsaturated fat. Use vegetable oil and butter sparingly. The goal in reducing fat intake is mainly for weight purposes.

4. Maintain or achieve desirable body weight. Those who are obese, more than twenty pounds over their ideal weight for height, should lose weight. Those who are mildly overweight should watch out for insidious weight gain.

There is controversy regarding eating red meat for the HCV-infected person. There is preliminary and limited research suggesting that iron accumulation in the liver may accelerate HCV progression, so some think that eating red meat or eating excessive amounts of red meat may contribute to iron accumulation in the liver. However, it has not been established by research that eating red meat actually has the clinical effect of accelerating HCV. If a person has decompensated liver disease certain diet restriction is considered. Many leading hepatitis doctors do not feel restricting intake of red meat is recommended for HCV-infected patients with chronic infection. It is important to bear in mind that in a person co-infected with HIV and HCV, anemia may be a concern and adequate intake of red meat may be important.

Marion Peters, MD, Hepatologist and GI specialist at UCSF says: if a patient has encepholopathy, which can occur as part of decompensated cirrhosis, they should limit their protein intake, but not necessarily eliminate red meat. Iron accumulation can be a problem only if you eat excessive amounts of red meat. Otherwise, eating red meat is fine and in fact could be part of your diet. Just don't eat red meat three times per day. If you are taking HCV therapy (Interferon, Interferon/Ribavirin) you should indulge yourself a little to increase caloric intake and particularly it's ok to eat red meat. Dr. Peters says the studies suggesting iron accumulation in the liver can be a

problem is when iron intake is very high and excessive.

On the topic of iron storage in the liver and it's potential harm, Ms. Rodriguez says: From a nutrition perspective, the following is known--

1. Iron is poorly absorbed through the GI tract. Heme-iron (i.e. meats) has a better absorption rate but is not 100%. Non heme-iron (i.e. fortified flour, cereals, spinach, etc) is better absorbed with meats, yet still not at 100%. Therefore, at any given high iron meal a maximum of 40-50% of iron is absorbed.

2. During inflammation (i.e. fever) iron storage in liver is increased. Diabetics and certain substance abusers may have conditional hemochromatosis. (a hereditary disorder of iron metabolism characterized by excessive accumulation of iron in tissues, diabetes, liver dysfunction, and a bronze skin pigmentation).

3. As for HCV, earlier studies suggested that increased liver iron levels elicit liver oxidative stress, with consequent steatosis (fatty liver) and glutathione depletion. (Iron storage, lipid peroxidation and gluthathione turnover in chronic anti-HCV positive hepatitis. J. Hepatol 1995 Apr;22 (4):44-56 , Therapy of hepatitis C: other options. Hepatology 1997 Sep;26 (Suppl 1): 143S - 151S.)

For HCV+ individuals it is reccomended not to take iron supplementation. If taking a multiple vitamin get one that says 'no iron' on the bottle. Ms Rodriguez says the question of whether to restrict iron intake needs to be considered individually, taking into consideration person's dietary habits, bloodwork, meds, physical health, and medical history. It is safe to say, that for men with elevated iron levels (serum ferritin especially), taking a multivitamin without iron is recommended.

CDC Hepatitis C Coordinators Conference: brief selected highlights. Remember the Alamo.

Jules Levin Executive Director, NATAP

The 9th Annual CDC Hepatitis C Coordinators Conference was held in San Antonio, TX this year. The conference is mainly a gathering of CDC (Centers for Disease Control) Hepatitis C coordinators. The conference hotel was across the street from the Alamo, and as I stood in the overcast but warm air, I thought to myself, our fight against hepatitis C is also a tough battle. Funding from Congress and the Administration is not forthcoming to support hepatitis C needs.

Several hundred coordinators and additional state and local officials and CDC officials are present to discuss and review hepatitis A, B, and C initiatives, research, and plans. The focus is not on broad treatment research reviews but on government programs on local levels, which are related to testing and counseling.

This brief article will report selected highlights of information I think would be of interest to you. Some interesting data has been presented here and some of the discussions have been interesting.

At HIV clinics in Texas a survey found that 23% had hepatitis C and 25% of individuals who were HCV+ had normal ALT (liver enzymes). Studies show that perhaps 12% of individuals with normal ALT will have fibrosis of stage 2 or worse. But in co-infected patients a significantly higher percentage with normal ALT have fibrosis and I have heard from various sources of numbers ranging from about 20% up to as many as 50% of patients with normal ALT have fibrosis. In the Texas study one-third of those surveyed in prison had HCV.

In another study presented by the CDC, among populations with high risk for HBV only 20-30% receive HBV vaccine and only 35% are tested for HIV.

There are 17,000 individuals on the transplantation wait list. HCV is the leading cause for liver transplantation.

The Collaborative IDU Study II was conducted from 1997-1999 among IDUs 18-30 years old. Study results reported HCV prevalence in selected cities: Los Angeles 20%; Chicago 30%; New Orleans 35%; New York 40% in the Lower Eastside, 50% in Harlem; Baltimore 55%. Overall HCV prevalence was 36%. Co-infection (HCV/HIV) prevalence was a stunningly low 3%, and so was the HIV prevalence of 4.7%. HBV prevalence was 22%. Another interesting piece of data was that in Harlem, the Lower Eastside in NYC, and Chicago, the 3 areas examined, the incidence (new infections) of HCV among IDUs was 16% per year. This is very interesting because a previous study from Baltimore reported that 80% of IDUs get HCV infected within the first year of injecting. This new data shows new infection occurring at 16% per year suggesting it would take 5 years for IDUs to collectively reach 80% prevalence. This is important because in treatment studies it is presumed that the duration of HCV infection for the study subjects is based on infection within the first year of IDU. Perhaps, in less densely populated areas than NY and Chicago it might take longer than 5 years for IDUs to get HCV infected. With the availability of clean syringes, perhaps it might take even longer on average for IDUs to get HCV infected.

There was some discussion regarding why there were low rates for HIV and HCV/HIV co-infection in this study. One contributing plausible reason is wider use of clean syringes from needle exchange programs. In particular, since this study is in younger IDUs the concept of using clean syringes has changed behavior patterns where clean needle programs are available. Co-infection rates are likely higher among older IDUs.

In another study of HCV testing in jails, 1020 interviews were conducted. Among illicit drug users 16% reported IDU, and among IDUs 82% had HCV. If a person had HIV they were 3.5 times more likely to have HCV. If the person was an IDU they were 55 times more likely to have HCV. 34% of thewomen were IDUs. There was some discussion in this workshop regarding why women appear to have such high HCV prevalence rates. Women may be more likely to be injected by men after men use a syringe; women may have multiple sex partners who are IDUs and have HCV; and women may be more likely to share needles more often with multiple men.

Active IV Drug Users & Individuals on Methadone Maintenance Can Be Successfully Treated For Hepatitis C: a multi-disciplinary approach

Diana L. Sylvestre, MD

Although injection drug users (IDUs) have the highest HCV infection rates of any behavioral risk group, they are the least likely to be offered treatment due to concerns about psychiatric disease, relapse to drug use, reinfection, and poor adherence. O.A.S.I.S. (Organization to Achieve Solutions in Substance-Abuse), a nonprofit clinic located in Oakland, CA, is on the forefront of developing evidence-based approaches to HCV treatment in IDUs as a means of addressing this disparity.

In the context of a unique group treatment approach, O.A.S.I.S. has screened over 1200 IDUs for HCV and treated nearly 200. Compared with "typical" HCV patients, O.A.S.I.S. patients are older, more gender and race balanced, and are therefore more representative of HCV-infected persons in the US. The majority of patients have a previous diagnosis of psychiatric illness. The median length of HCV infection is over a decade longer than that seen in most studies.

Because of methadone's stabilizing properties, O.A.S.I.S. initially studied treatment outcomes for the hepatitis C virus in recovering heroin users maintained on methadone. Seventy-six patients were enrolled. Their average age was 50; 71% were white, 13% were black, and 16% were Latino. Sixty-four percent had a history of heavy alcohol use, 30% had been sober for <6 months, and 59% reported a pre-existing psychiatric diagnosis. The majority (60%) had genotype 1, and 26% had cirrhosis. During HCV treatment, 20% drank alcohol and 34% used hard drugs.

Despite these challenging characteristics, the patients in this study responded well to interferon alfa-2b/ribavirin combination therapy: overall, 28% achieved a sustained virologic response (SVR), and the SVR of those who completed treatment was 36%. Eighteen patients (24%) discontinued therapy, but discontinuations were not correlated with gender, race, genotype, psychiatric disease, alcohol ingestion, or hard drug use.

Interestingly, only a history of psychiatric disease was statistically predictive of negative treatment outcomes. Although there were modest decrements in outcomes in those with <6 months of sobriety and those who used hard drugs, these did not achieve statistical significance, suggesting that the impact of these barriers is less than typically assumed. However, none of the eight subjects who relapsed to regular drug use achieved an SVR, suggesting that more aggressive support and intervention may be needed in this setting. In addition, marijuana use led to a significant improvement in SVR, likely related to improved adherence rates.

These results suggest that HCV treatment can be successful even in active drug users, in a setting that can address their special needs. Although substance use may be associated with reduced treatment responses, a significant proportion of patients still benefit. In light of these findings, a strategy that focuses on aggressive psychiatric intervention, side effect management, and preventing relapse to regular drug use will assist a substantial proportion of IDUs with successfully completing therapy.

HCV/HIV Co-infection Congressional Briefing

Michaela Leslie-Rule

Washington, DC – Tuesday, March 25, 2003 - HIV/HCV Co-infection briefing in the U.S. House of Representatives sponsored by National AIDS Treatment Advocacy Project and Congressional Black Caucus members, Delegate Donna Christian-Christensen (V.I.) and Rep. Edolphus "Ed" Towns (NY-10).

Over 100 people attended last week's briefing on HIV and Hepatitis C virus co-infection held in the U.S. House of Representatives. The event drew advocates, community leaders and representatives from all over the country, including 25 community members from New York City and Hepatitis C advocate Luther Brock from Oakland, California. The day was a milestone event and could initiate progress towards recognizing Hepatitis C and co-infection as a national epidemic.

Delegate Christian-Christensen opened the briefing with some brief words about the gravity of this epidemic saying "1 in 15 persons are affected with HCV worldwide" and that the African-American community is disproportionately affected by this epidemic. Representative Towns was unable to attend the event, but was represented by Sheri Brownston who welcomed the attendees on his behalf. Ms. Brownston sited the need for more research dedicated to preventative and therapeutic treatment for co-infected individuals and treatment protocols.

Presentations were made by: Doctor Henry "Skip" Francis of the National Institute of Health and Dr. Dickens Theodore of University of North Carolina, Chapel Hill. Dr. Francis described the changing HCV disease burden in the United States as a result of injection drug use and Dr. Theodore discussed the epidemiology and treatment of the HCV virus. In addition Heather Timmermans, Director of the Co-Infection Clinic at Brooklyn Hospital, discussed a model co-infection clinic and the impact of HCV on HIV affected individuals in the community she serves. Thelma Thiel of Hepatitis Foundation International spoke about the need for prevention programs.

Jules Levin, Executive Director/Founder of NATAP, moderated the hearing. Mr. Levin who has himself been co-infected for 20

years, discussed the needs of co-infected patients and emphasized a need for policy that provides funding for HCV testing, prevention, education and support services.

Several Congressional Black Caucus members sent representatives from their offices including Rep. John Conyers (MI-14), Rep. Elijah Cummings (MD-7) and Rep. Donald Payne (NJ-10). Mr. Conyers and Mr. Payne attended the meeting in person and several key attendees expressed an interest in facilitating government support of this issue.

Although not on the agenda, Rep. Conyers spontaneously addressed the attendees saying that there was a need for a second session on HIV/HCV Co-infection. "Where do we go from here? Now that we know there is a problem, what are we going to do about it?" He suggested that in collaboration with Rep. Towns and Delegate Christian-Christensen, his office would co-sponsor a meeting to discuss legislative action and policy to address the co-infection epidemic.

Check Out NATAP's Upcoming Events

To register fill out the following information and Fax or mail to NATAP. Be sure to write clearly and to check the box next to each event you would like to attend.

This is my:

☐ Home Or ☐ Work (please check one)

First Name _____

Last Name _____

City _____

State _____ Zip _____

Work Phone _____

Home Phone _____

Affiliation _____

Email _____

Fax _____

Please check the boxes of the events that you are registering for:

☐ **Women & HIV with Mary Vogler, MD**
Monday, April 28th 2003, from 1:00PM to 4:00PM
NYU Medical Center
550 1st Avenue (between 31st and 32nd Sts)
Alumni Auditorium A (Downstairs)

☐ **Hepatitis C/HIV Co-infection Support Group**
(meets monthly)
Tuesday, May 13th From 5:00pm to 7:00pm
NATAP Office
580 Broadway Suite 1010
New York, NY 10012

☐ **HIV Treatment and Treatment Options**
with Charles Gonzalez, MD, PHD
NYU Medical Center
Thursday, May 15th 2003, from 1:00PM to 4:00PM
NYU Medical Center
550 1st Avenue (between 31st and 32nd Sts)
Alumni Auditorium A (Downstairs)

☐ **A Discussion of HIV/AIDS & Hepatitis C**
Thursday May 15, 2003
10:00am - 3:30pm
The Curriculum Center
St. Croix, VI

☐ **A Discussion of HIV/AIDS & Hepatitis C**
Friday May 16, 2003
10:00am - 3:30pm
St. Thomas, VI

☐ **Entrenamiento Actualizado Sobre VIH y su Tratamiento**
Domingo, Mayo 18, 2003, Hora: 9:30am to 3:00pm
NY Presbyterian Hospital-Milstein Building
177 West Fort Washington Ave. (entre 165st & 168st) New York, NY
Clark Conference Center 1er Piso

☐ **HCV and Hepatitis C / HIV Co-infection**
Friday, May 23, from 10:00am to 2:00pm
Woodhull Hospital
760 Broadway (corner of Flushing Ave.)
3rd Floor The Dolores Jackson Auditorium
Brooklyn, NY 11206

National AIDS Treatment Advocacy Project (NATAP)
580 Broadway, Suite 1010
New York, NY 10012
Tel: (212) 219-0106
Fax: (212) 219-8473
Email: info@natap.org
Treatment Website: www.natap.org